



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/717,226

11/19/2003

Ji-Young Kim

39894-00601

6919

29880

7590

05/28/2008

FOX ROTHSCHILD LLP

PRINCETON PIKE CORPORATE CENTER

997 LENOX DRIVE, BUILDING #3

LAWRENCEVILLE, NJ 08648

EXAMINER

ROBERTS, LEZAH

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

05/28/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/717,226

Applicant(s)

KIM ET AL.

Examiner

LEZAH W. ROBERTS

Art Unit

1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 158-164, 166-202, 205-207, 215 and 216 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 158-164, 166-202, 205-207, 215 and 216 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This Office Action is in response to the amendment filed February 18, 2008. All previous rejections have been withdrawn unless stated below.

The indicated allowability of the claims is withdrawn in view of the newly discovered reference(s) to Chen. Rejections based on the newly cited reference(s) follow.

This action is made NON-FINAL.

Claims

Claim Rejections - 35 USC § 112 – Indefiniteness (New Rejection)

Claims 158-164, 166-172, 187-202, 205-207, 215 and 216 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1) Claims 158 and 187 recite the limitation "wherein the patch has adhesive strength, and wherein the adhesive strength of the patch will increase upon becoming hydrated". This is indefinite insofar as the patch is dry and accordingly should have no adhesive strength until it is hydrated. Therefore the patch will acquire an adhesive strength; the adhesive strength will not increase.

2) Claims 205, 215 and 216 recite the limitation "the adhesive layer is in a dry state and has adhesive strength. The claims are indefinite insofar as it is unclear how the patch can have adhesive strength when it is in a dry state. The recitation of dry state indicates the patches are dry and therefore will not stick to a surface unless it is hydrated.

3) Claim 188 recites the limitation "wherein the adhesive strength of the patch, upon becoming hydrated, at least doubles as compared to the dry state". The claims is indefinite insofar as the patch is not adhesive when it dries, therefore "at least doubles" is indefinite because double of zero is zero or undefined.

Claim Rejections - 35 USC § 103 – Obviousness (New Rejection)

1) Claims 158-164, 168-180, 183-195, 198-202, 205-207, 215 and 216 are rejected under 35 U.S.C. 103(a) as being unpatentable over McAnalley et al. (US 5,409,703) in view of Jenkins et al. (US 4,940,587) and Chen (US 5,641,530).

McAnalley et al. disclose dried hydrogel compositions comprising therapeutic agents. The dried hydrogel can be transformed to a hydrogel upon absorption of addition liquid medium (see Abstract). The hydrogel is self-adherent when wet (col. 12, lines 20-22). The compositions may be used in the oral cavity. Polymers that are used in the hydrogels include polyvinyl pyrrolidone (col. 13, lines 60-67). One example discloses Plasdane (polyvinyl pyrrolidone) and hydrogen peroxide. The hydrogen

peroxide is disclosed at about 4% when the composition disclose in Table two is dried. Polyvinyl pyrrolidone may be considered a stabilizer for hydrogen peroxide, as stated in the previous Office Action. The compositions may further comprise hydroxy ethyl cellulose. The hydrogel is placed on a sheet, which encompasses a backing layer. The compositions may comprise antibiotics, anesthetics and other pharmaceutical agents. The reference differs from the instant claims insofar as it does not disclose the composition comprises sodium tripolyphosphate or hydroxypropyl methyl cellulose.

Jenkins et al. is used as a general teaching to show different hydroxyalkyl cellulose polymers are at times used interchangeably (as equivalents) in compositions that deliver pharmaceuticals to the mucosa of the oral cavity. These include hydroxypropylmethyl, hydroxypropyl, hydroxyethyl and hydroxymethyl cellulose (col. 2, lines 53-65). The reference differs from the instant claim insofar as it does not disclose the hydroxypropylmethyl cellulose was incorporated into compositions comprising hydrogen peroxide, tripolyphosphate and polyvinyl pyrrolidone.

Chen discloses disinfection of foodstuff involving using hydrogen peroxide in combination with anti-microbial agents. Anti-microbial activity was seen with a combination of peroxide and sodium tripolyphosphate.

It is obvious to replace one component for another equivalent component if it is recognized in the art that two components are equivalent and is not based on the Applicant disclosure. See In re Ruff, 256 F.2d 590, 118 USPQ 340 (CCPA 1958); see also In re Scott, 323 F.2d 1016, 139 USPQ 297. It is also prima facie obviousness to select a known material based on its suitability for its intended use. See Sinclair &

Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945). Also, established precedent holds that it is generally obvious to add known ingredients to known compositions with the expectation of obtaining their known function. See, e.g., In re Linder, 457 F.2d 506, 507 (CCPA 1972); see also In re Dial, 326 F.2d 430, 432 (CCPA 1964). It would have been obvious to one of ordinary skill in the art to have used hydroxypropylmethyl cellulose in place of hydroxyethyl cellulose as a hydrophilic material in the compositions of the primary reference based on the prior art's recognition that such species are equivalent in function, as supported by cited precedent.

It would also have been obvious to one of ordinary skill in the art to have used sodium tripolyphosphate in the compositions of the primary reference motivated by the desire to use component that would enhance the anti-microbial activity of hydrogen peroxide as disclosed by Chen.

2) Claims 166, 181, 182, 196 and 197 are rejected under 35 U.S.C. 103(a) as being unpatentable over McAnalley et al. (US 5,409,703) in view of Jenkins et al. (US 4,940,587) and Chen (US 5,641,530) as applied to claims 158-164, 168-180, 183-195, 198-202, 205-207, 215 and 216 in further view of Frate et al. (US 2001/0049417).

The references, McAnalley et al., Jenkins et al. and Chen, are discussed above. The references differ from the instant claims insofar as it does not disclose the compositions comprise a plasticizer.

Frate et al. is used as a general teaching to disclose conventional additives used in hydrogel compositions. The additives include humectants such as glycerin, propylene

Art Unit: 1612

glycol and sorbitol (paragraph 0073). The reference differs from the instant claims insofar as it does not disclose the plasticizers are incorporated into compositions comprising hydrogen peroxide and polyvinyl pyrrolidone.

It is *prima facie* obviousness to select a known material based on its suitability for its intended use. See *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). Also, established precedent holds that it is generally obvious to add known ingredients to known compositions with the expectation of obtaining their known function. See, e.g., *In re Linder*, 457 F.2d 506, 507 (CCPA 1972); see also *In re Dial*, 326 F.2d 430, 432 (CCPA 1964). It would have been obvious to one of ordinary skill in the art to have incorporated a humectant such as glycerin into the compositions of the primary reference motivated by the desire to use the humectant for its specific function, as supported by cited precedent.

Claims 158-164, 166-202, 205-207, 215 and 216 are rejected.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone

Art Unit: 1612

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612